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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,817	03/27/2006	Walter Gumbrecht	32860-00901/US	1151

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EXAMINER

EDWARDS, LYDIA E

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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10/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,817	Applicant(s) GUMBRECHT ET AL.	
	Examiner LYDIA EDWARDS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see amendment, filed 5/12/2008, with respect to the rejection(s) of claim(s) 1-18 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection follows.

Applicant's arguments, see amendment, filed 5/12/2008, with respect to the rejections of 7 and 15 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The 35 U.S.C. 112 rejections of claims 7 and 15 have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 6-8, 11-12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable Blackburn et al. (US 7087148) in view of Albers et al. (WO 00/62048). Regarding Albers et al. (WO 00/62048), which was not published in English, the US equivalent US 7208077 was used as an English translation.

Regarding Claim 1, Blackburn et al. ('148) discloses DNA chip, comprising: a carrier, arranged on the carrier containing immobilized catcher molecules (capture probe), containing a thin-film four pole system for the impedance-spectroscopic detection of binding events between the catcher molecules and target molecules of an analyte solution applied to the spots, the thin film four pole system including two polarization and two sensor electrodes but does disclose an analogous thin film (Col 3, line 52-Col 4, line 20; Col 8, lines 43-51; Col 10, lines 30-38; Col 11, lines 13-34; Col 12, lines 22-29). Blackburn does not explicitly state wherein, a microarray of spots is arranged thereon the carrier.

Albers et al. ('077) discloses the production of dot shaped ultramicroelectrodes having a size of 1-2 micrometers (Col 13, Lines 46-64).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Blackburn with an array of dot shaped ultramicroelectrodes of Albers in order to provide an array arrangement for a multi analyte measurement.

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Regarding Claim 2, Blackburn et al ('148) discloses a microchip wherein the carrier includes a silicon substrate on which the microelectrode system is integrated using thin-film technology (Col 95, lines 15-30).

Regarding Claims 6 and 14, Blackburn et al ('148) does not explicitly state wherein at least one of at least one sensor electrode and at least one shielding electrode are directly electrically isolated from the analyte, however he does state (Col 12, lines 44-46) that the detection (sensor) electrode may be configured in a variety of ways.

It would have been obvious to one having ordinary skill in the art at the time the invention made to allow for direct electric isolation in order to prevent any unexpected charge, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding Claims 7 and 15, Blackburn et al ('148) does not explicitly state wherein a sensor electrode contains pointlike individual electrodes which are electrically connected to a buried electrode collective line by way of plated-through holes, however he does state (Col 12, lines 22-37) that the electrode may be in the form of a tube and various other conformations. Therefore the examiner deems the device of Blackburn capable of being configured with pointlike individual electrodes.

It would have been obvious to one having ordinary skill in the art at the time the invention made to modify Blackburn with pointlike individual electrodes which are electrically connected to a buried electrode collective line by way of plated-through holes in order to form a detection zone for interrogation of test samples.

Regarding Claims 11 and 17, Blackburn et al ('148) does not explicitly state wherein the reaction layer is a hydrogel.

Albers et al ('077) discloses wherein the reaction layer is a hydrogel (Col 23, lines 10-48).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Blackburn with a hydrogel reaction layer as taught by Albers to provide improved allocation of binding processes to individual array positions by inhibiting diffusion.

Regarding Claims 12 and 18, Blackburn et al. ('148) discloses wherein the thin-film four-pole system forms an interdigital current electrode arrangement but does not explicitly state wherein double meandering current taps are used (Col 12, lines 36-43).

Albers et al ('077) discloses wherein the thin-film four-pole system forms an interdigital current electrode arrangement with double meandering current taps (Col 12, line 66-Col 13, line 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Blackburn with meandering configuration as taught by Albers in order to provide an alternate detection means based on the specified detection method.

Regarding Claims 8 and 16, Blackburn et al ('148) does not explicitly state wherein the thin-film microelectrode system is embedded in a reaction layer containing catcher molecules.

Albers et al ('077) discloses wherein the thin-film microelectrode system is embedded in a reaction layer containing catcher molecules (Col 23, lines 21-48).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to embed the microelectrode system of Blackburn in a reaction layer as taught by Albers to further facilitate the analyte detection process.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn et al. (US 7087148) in view of Albers et al. (WO 00/62048) as applied to claim 1 above, and further in light of Cote (US 6485703).

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Regarding Claim 9, Albers et al ('077) teaches hydrogel layer but silent about the reaction layer thickness. However, the size of the reaction layer thickness was known in the art at the time of the claimed invention was made as taught by Cote et al, who teaches thickness of the hydrogel film, i.e., reaction layer is 100 micrometer (Col 41, lines 54-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a reaction layer of reasonable size in respect to the width of the microfluidic device as taught by Cote, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ

Regarding Claim 10, Albers et al ('077) teaches that the electrode has a width of 1 micrometer and the spacing of 0.9 micrometer (column 26, lines 35-37) and silent about reaction layer thickness. The rejection above is relied upon.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to design an electrode of reasonable size to provide a portable biosensor system for the rapid detection of pathogenic bacteria as taught by Albers.

Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn et al. (US 7087148) in view of Albers et al. (WO 00/62048) as applied to claim 1 above and, further in view Burns et al. (US 20020172969).

Regarding Claims 3 and 13, Blackburn et al ('148) does not disclose a shielding electrode. Burns et al. ('969) discloses the use of a shielding electrode in a similar chip based device (Paragraphs 198 and 384)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to assign a shielding electrode of Burns to the sensor electrode of Blackburn in order to eliminate spurious signals.

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Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn et al. (US 7087148) in view of Albers et al. (WO 00/62048) further in view Burns et al. (US 20020172969) as applied above to claim 3 and further in view of Gau (WO 01183674).

Regarding Claim 4, Blackburn et al ('148) does not disclose, wherein the electrical potential of the sensor electrode is held at the shielding electrode by a buffer amplifier connected to the sensor electrode and having a gain of 1.

Gau ('674) discloses wherein the electrical potential of the working electrode is held at the reference electrode potential by a buffer amplifier connected to the working electrode and having a gain of 1 (Page 1, lines 24-38 and figure 1).

It is well known in the art that if the voltage transferred is unchanged, then there is a gain of 1 and the amplifier is a unity gain buffer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Blackburn et al. with a buffer amplifier as taught by Gau in order to ensure that the required cell polarization is achieved and maintained.

Regarding Claim 5, Blackburn et al ('148) does not disclose, wherein the buffer amplifier is integrated on the carrier.

Gau ('674) discloses wherein the buffer amplifier is integrated on the carrier (Abstract and figure 1-2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Blackburn et al. with a buffer amplifier integrated on the carrier as taught by Gau in order to provide rapid detection of pathogenic bacteria in addition to portability of the biosensor system.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lydia Edwards whose telephone number is 571.270.3242. The examiner can normally be reached on Mon-Thur 6:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lydia Edwards

Examiner

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LE

/Walter D. Griffin/

Supervisory Patent Examiner, Art Unit 1797